



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 685,403	10 10 2000	Peter R. Beetham	7991-086	4644

23493 7590 09 11 2002

SUGHRUE MION, PLLC
1010 EL CAMINO REAL, SUITE 300
MENLO PARK, CA 94025

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 09 11 2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/685,403

Applicant(s)

BEETHAM ET AL.

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 June 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. _____.
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s):

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO 1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed 18 June 2002.
2. Claim 24 has been cancelled without prejudice or disclaimer.
3. The Examiner notes that Applicant has summarized reference B1 of the IDS filed 8 June 2001, which was not considered previously because of a lack of an English translation of a foreign document.
4. The rejection of claims 14-22 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn in view of Applicant's amendments to said claims.
5. The rejection of claims 1-23 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is withdrawn in view of Applicant's arguments on pages 5-6 of the Remarks.
6. The rejection of claims 20-23 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Lebrun *et al* (WO 97/04103) is withdrawn in view of Applicant's amendments to said claims.
7. The rejection of claims 1-23 under 35 U.S.C. § 103(a) as being unpatentable over Kmiec (U.S. Patent 5,756,325), filing date September 9, 1996, in view of Lebrun *et al* (WO 97/04103) is withdrawn in view of Applicant's arguments on page 8 of the

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

9. Formal drawings were received on 18 June 2002. The Draftsman has objected to these drawings. See the attached for PTO-948. Applicant is reminded that correction of the drawings cannot be held in abeyance, and that new formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Claim Rejections - 35 USC § 101

10. Claims 1-13 remain rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. This rejection is repeated for the reasons of record in the last Office Action mailed 13 February 2002.

The Examiner notes that Applicant has amended the instant claims according to the Examiner's suggestion. The Examiner has reconsidered the rejection and the suggested wording of the instant claims for the following reasons. The instant invention is directed to a method of *in situ* mutation of genes, specifically the EPSPS gene endogenous in plants, and herbicide resistant plants produced by such a method. Said method is a new technology and application of this technology in plants was not commonly practiced in the art at the time of Applicant's invention. The issue in the

rejection is whether the claimed invention is directed to a product produced by the claimed method.

Without convincing evidence to the contrary, it is the Examiner's opinion that one of skill in the art at the time of Applicant's invention would not have been able to distinguish the product of the claimed method from a naturally occurring mutant plant comprising a mutant, herbicide resistant EPSPS enzyme.

Claim Rejections - 35 USC § 102 and 103

11. Claims 1-23 remain rejected under 35 U.S.C. § 102(a) as being anticipated by Hawkes *et al* (WO 98/54330). This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 February 2002. Applicant's remarks filed 18 June 2002 have been fully considered but they are not relevant to the instant rejection.

Applicant notifies the Examiner that the instant application is commonly assigned with Valigen (US) Inc. with U.S. Patent Application 09/424,344, filed 22 November 1999, which was filed under 35 U.S.C. § 371 from WO 98/54330, filed 22 May 1998.

Applicant does not present any arguments to the instant rejection. Common assignment is irrelevant in the instant case because the instant invention was previously disclosed by Hawkes *et al*, a different inventive entity without a common inventor and not commonly assigned at the time of the invention, and was disclosed prior to Applicant's invention. The issue of common assignment of the instant invention and the US Patent Application 09/424,344 will be address below.

12. Claims 1-13 remain rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Lebrun *et al* (WO 97/04103).

Art Unit: 1638

mailed 13 February 2002. Applicant's arguments filed 18 June 2002 have been fully considered but they are not persuasive.

Applicant argues that Lebrun involves the transformation of heterologous mutant EPSPS genes resulting in transformed plant that contain an inserted gene (see page 7 of the remarks). This is not found to be persuasive because Lebrun on pages 5-7 discloses a Black Mexican Sweet corn cell culture that comprises a mutant EPSPS gene, that was not introduced by transformation. Hence, the cells comprised a mutant, herbicide resistant EPSPS gene. Hence, the instant claimed plants would not be distinguishable from the mutant cell or plants regenerated therefrom disclosed by Lebrun. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. In the instant case, the plants produced by the claimed process would not be distinguishable from naturally occurring mutant plants comprising a mutated EPSPS gene, plants produced by *in vitro* mutagenesis methods using chemicals or selection pressure in culture, or by any other *in vivo*-site directed mutagenesis methods in plants.

13. Claims 1-23 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application 09/424,344, James *et al* filed 22 November 1999.

The applied reference has a common assignee with the instant application.

Under 35 U.S.C. § 102(b), this rejection under 35 U.S.C. § 102(e) might be overcome

Art Unit: 1638

either by a showing under 37 CFR § 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR § 1.131.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

15. Claims 1-23 are rejected under 35 U.S.C. § 102(f) and (g)(2) because the applicant did not invent the claimed subject matter or the instant Applicant was not the first to invent the claimed subject matter. This rejection is made in view of Applicant's statement on page 7, 1st paragraph of the Remarks filed 18 June 2002 that a co-pending application 09/424,344, which was not commonly assigned at the time of Applicant's invention, is now commonly assigned to Valigen (US) Inc. The co-pending applications disclose common subject matter.

Double Patenting

16. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tying of two distinct inventions into one claim.

USPQ 645 (Fed. Cir. 1985); *in re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

Art Unit: 1638

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR § 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR § 3.73(b).

17. Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 15, 16, 18, and 21-24 of commonly assigned US Patent Application 09/424,344. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to the same subject matter as those of the co-pending application, that being *in situ* mutagenesis of a plant EPSPS gene and herbicide resistant plants produced therefrom.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Inventorship

18. Claims 1-23 are directed to an invention not patentably distinct from claims 1, 15, 16, 18, and 21-24 of commonly assigned US Patent Application 09/424,344. Specifically, the claims of the instant application are directed to the same subject matter as the claims of the commonly assigned application.

The U.S. Patent and Trademark Office normally will not institute an interference

between the instant application and commonly assigned US Patent Application 09/424,344, discussed above.

Art Unit: 1638

would form the basis for a rejection of the noted claims under 35 U.S.C. § 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR § 1.78(c) and 35 U.S.C. § 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. §§ 102(f) or (g), or 35 U.S.C. § 102(e) for applications filed on or after November 29, 1999.

Conclusion

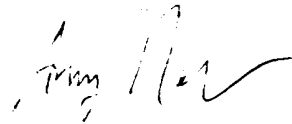
19. This Office Action is non-final
20. No claims are allowed.
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

number for this group is (703) 306-4539. Before final action (703) 306-4539. After final,

Art Unit: 1638

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

David H. Kruse, Ph.D.
5 September 2002